UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE BIOAGE LABS, INC., SECURITIES LITIGATION

Case No. 25-cv-00196-RS

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS WITH LEAVE TO AMEND

The Southeast Pennsylvania Transportation Authority ("SEPTA"), on behalf of itself and a putative class of similarly situated investors, sued BioAge Labs and ten of its corporate officers under two provisions of the Securities Act of 1933, 15 U.S.C. §§ 77k, o. SEPTA alleges that, in the run-up to its initial public offering, BioAge misled investors by omitting from its registration statement and prospectus (collectively, the "offering documents") critical information about the safety of its leading drug candidate and the concomitant risks to its ongoing Phase 2 clinical trial. *See* Dkt. 46 (CAC). BioAge moves to dismiss for failure to state a claim under Rule 12(b)(6). *See* Dkt. 50. Because the allegations in the complaint fail plausibly to allege a violation of the securities laws, Defendants' motion is granted with leave to amend.

I. BACKGROUND

BioAge is a clinical-stage biopharmaceutical company focused on developing drug therapies to treat metabolic diseases associated with aging, such as obesity and muscle atrophy. *See* CAC ¶ 39. At the time of its initial public offering, BioAge's lead product candidate was a small-molecule drug called azelaprag. Azelaprag was originally developed by Amgen as a

treatment for heart failure. *Id.* ¶ 52. After Amgen abandoned that use-case, it granted BioAge an exclusive license to research, develop, and commercialize azelaprag. *See id.* ¶ 53. In simple terms, BioAge's hypothesis was that azelaprag could facilitate weight loss by mimicking the physiological response to exercise. BioAge estimated that, if successful, azelaprag could be worth approximately $150 billion by 2031. *See id.*

Testing of azelaprag proceeded in several phases. It was first tested on mice. *See* CAC ¶ 56. As explained in its offering documents, the mouse studies demonstrated that, administered alone, azelaprag "resulted in significantly improved body composition (% lean, % fat) in mice challenged in a high-fat diet." *Id.* ¶ 58. The mouse studies also showed that when combined with a second drug called tirzepatide—which regulates blood sugar and appetite—azelaprag "restored body weight and body composition of obese mice to lean control levels." *Id.* ¶ 59. The offering documents did not report any adverse safety observations from the mouse studies.

After the preclinical mouse studies, azelaprag underwent eight Phase 1 clinical trials which, in total, involved 265 human participants. CAC ¶ 70. In the offering documents, BioAge represented that "azelaprag was well-tolerated" in the trials' participants and exhibited an "overall adverse event profile . . . comparable to placebo, with no treatment-related trends in adverse events observed, with the exception of mild, self-limited headaches." CAC ¶ 70. It further represented that "[n]o serious adverse events have been reported." *Id.*

Roughly two months before its IPO, BioAge announced the start of the STRIDES Phase 2 clinical trial. *See* CAC ¶ 45. The STRIDES trial's objective was to test azelaprag in obese individuals over 55-years old in combination with tirzepatide. *See id.* BioAge tested four cohorts—those receiving only azelaprag, those receiving only tirzepatide, those receiving both, and a placebo group—across multiple dosages. *See id.* ¶ 48, 112. BioAge said in its offering documents that it anticipated topline results from the STRIDES trial in the third quarter of 2025. *See id.* ¶ 48.

The offering documents discussed the risks to its development of azelaprag and, consequently, BioAge's commercial prospects. They explained, for instance, that "[BioAge's] business could be harmed if results of [its] ongoing or planned clinical trials of azelaprag show

unexpected adverse events or a lack of efficacy in the indications [it] intend[s] to treat." CAC ¶ 102. They further warned investors that "[i]f additional adverse events, serious adverse events (SAEs) or other side effects are observed in any of [its] clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of [its] product candidates are a part of . . . [it] may be required to abandon those trials or [its] development efforts of one or more product candidates altogether." *Id.*

Buoyed by enthusiasm around azelaprag, BioAge successfully hit the market. It sold 11 million shares at $18 per share, raising a total of $198 million. CAC ¶ 7. Within a month of the offering, the stock was trading above $25 per share. *See id.* However, in December 2024—only about nine weeks after its IPO—BioAge announced that it was discontinuing the STRIDES trial. On the day of the announcement, BioAge's stock fell from $20.09 per share to $4.65 per share. *See id.* ¶ 115. In January 2025, BioAge confirmed that it had abandoned the development of azelaprag. *See id.* The stock has not since recovered.

BioAge reported that it discontinued the STRIDES trial because 11 participants dosed with azelaprag developed transaminitis. *See id.* ¶ 112. Transaminitis is characterized by elevated liver enzyme levels in the blood. *See id.* ¶ 36–37. Though transaminitis is not itself a disease, it is often indicative of some kind of injury to the liver. *See id.* ¶ 36. Transaminitis can have many causes ranging from serious to benign, including physical exercise and rapid, significant weight loss. *See id.* ¶ 37.

SEPTA filed this lawsuit on behalf of itself and other similarly situated investors, averring that BioAge and the corporate officer defendants are strictly liable for statements in the offering documents that were either false or misleading. Specifically, SEPTA contends that the offering documents failed to disclose that transaminitis presented a serious risk to the development and commercialization of azelaprag. In SEPTA's telling, transaminitis was "typical, expected, [and had] already materialized" in the 2018 Amgen Phase 1 clinical trial, making it "virtually certain to continue to occur in the STRIDES trial." Dkt. 56 (Opp.), at 1. Defendants have moved dismiss for failure to state a claim under Rule 12(b)(6). *See* Dkt. 50.

II. LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), the complaint must allege sufficient facts which, if accepted as true, "state a claim for relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

SEPTA brings claims under Sections 11 and 15 of the Securities Act of 1933. To state a claim under Section 11, SEPTA must plausibly aver that the offering documents "contained an untrue statement of material fact [or omission of] a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a); *see Rubke v. Capitol Bancorp Ltd*, 551 F.3d 1156, 1161 (9th Cir. 2009). Importantly, Section 11 does not create liability whenever an issuer withholds material information from the market. *Cf. Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 (2011). Rather, it compels disclosure only where the information is necessary to make the other statements in the offering documents not misleading. *Cf. id.* To state a claim for relief under Section 11, the plaintiff need not prove that the defendants acted with any intent to deceive or defraud. *See Omnicare, Inc. v. Laborers Dist. Council Const. Industry Pension Fund*, 575 U.S. 175, 179 (2015). Section 15 is a derivative provision which "makes controlling persons jointly and severally liable for violations of the Securities Act." *Pirani v. Slack Technologies, Inc.*, 127 F.4th 1183, 1187 (9th Cir. 2025); *see* 15 U.S.C. § 77o.

III. DISCUSSION

SEPTA's theory is that BioAge's failure to disclose the risk that transaminitis would derail the STRIDES trial rendered its discussion of the risks to the STRIDES trial misleading. That is because, in its view, transaminitis was not just another *possible* hazard, it was *the* hazard—one

that was "virtually certain" to occur because of the STRIDES trial's design and the properties of azelaprag. Opp., at 2. Therefore, SEPTA contends it was simply not possible to discuss accurately the risk that side effects of azelaprag would impact the STRIDES trial without expressly disclosing the risk posed by transaminitis.

This theory suffers from two defects—one primarily legal and one primarily factual. The legal proposition undergirding SEPTA's theory is that it is fundamentally misleading to fail to disclose a risk that will inevitably degrade the value of the company's securities. SEPTA locates that rule in an out-of-circuit decision, *Set Capital LLC v. Credit Suisse Grp. AG*, 996 F.3d 64 (2d Cir. 2021). That case involved disclosures made by Credit Suisse, an investment bank, in connection with the issuance of certain investment vehicles tied inversely to the volatility of the public equity markets. *See id.* at 69. The offering documents spoke equivocally about the risk to the value of the investment vehicles posed by Credit Suisse's hedging activity. *See id.* at 85. It advised purchasers that while "there can be no assurance" that the value of the investment vehicle would not be impacted, it had "no reason to believe that [its] . . . hedging activities will have a material impact on the level of the [investment]." *Id.* (second alteration in original). That was, as the Second Circuit put it, a "half-truth." *Id.* The complaint plausibly averred that Credit Suisse "knew with virtual certainty . . . [its] hedging activity would significantly depress the value of the [investment vehicles]" in part because it had done just that on three prior occasions. *See id.* at 85–86. In that context, "cautionary words about future risk" were insufficient because "the risk ha[d], in fact, materialized in the past and [was] virtually certain to materialize again." *Id.* at 85.

Credit Suisse's liability under Section 11 was created initially by its decision to speak about the risk posed by hedging. That is, once it decided to talk about hedging, it was obligated not to mislead investors about the nature of the risk. *See id.* at 86 ("[T]he Offering Documents misrepresented Credit Suisse's knowledge and intent when they warned that Credit Suisse's hedging activity 'could' or 'may' impact prices of [the investment vehicles] but affirmed that Credit Suisse had 'no reason to believe' that it would."). The opposite, however, is also true: Had Credit Suisse chosen not to talk about hedging at all, it would have been under no obligation to

disclose the risk that its hedging activity would devalue the investment vehicle even if that was inevitably going to happen.

Therefore, SEPTA must do more than aver that the risk of transaminitis was significant and inevitable. It must point to a statement in the offering documents that was misleading absent such a disclosure. Because it has not pointed to any statement minimizing the risk of transaminitis expressly, it falls back on the contention that inclusion of something implies the exclusion of all else. In essence, SEPTA argues that by discussing the risk that the STRIDES trial could be impacted by "unexpected" or "atypical" side effects, it implied that there was no risk of impact from "expected" or "typical" side effects.

That argument was rejected, however, in *In re Rigel Pharmaceuticals, Inc. Sec. Litig.*, 697 F.3d 869 (9th Cir. 2012). There, a putative class of investor-plaintiffs sued Rigel, a pharmaceutical corporation, under Section 11 for allegedly misleading disclosures related to a clinical trial of its lead product candidate. *See id.* at 871. Rigel elected to publish certain safety-related results from its clinical trial. *See id.* at 880. For instance, it published incidents of hypertension that were moderate or severe, incidents of increased liver enzymes that were at least three times the upper limit, and incidents of gastrointestinal distress that were moderate or severe. *See id.* at 880–81. The plaintiffs contended that those disclosures were misleading because they suggested that they were the *only* incidences of the various conditions. To avoid misleading investors, plaintiffs argued that "once a company chooses to disclose any safety information, it must disclose all material information regarding safety." *Id.* at 880 n.8. The Ninth Circuit, however, rejected that proposition, describing it as a misconstruction of Supreme Court precedent. *See id.*

Were it otherwise, Section 11 would effectively include a requirement that issuers disclose everything on a certain topic once they disclose anything on that topic, lest they be accused of implying that the unstated information did not exist. Such a requirement would functionally divest issuers over the control of information that Section 11 grants them. *Cf. Matrixx*, 563 U.S. at 45 (remarking, in a Section 10b-(5) case, that "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these

provisions by controlling what they say to the market"); *see Rubke v. Capitol Bancorp Ltd*, 551 F.3d 1156, 1163 (9th Cir. 2009) ("Section 11 does not require the disclosure of all information a potential investor might take into account when making his decision . . .").

At bottom, SEPTA's theory falls within that which *Rigel* rejected. SEPTA does not aver that BioAge disclosed the risk of transaminitis but did so in a misleading way. Nor does it aver that BioAge selectively presented safety results from its testing of azelaprag. It avers that the risk disclosures were inherently misleading absent a discussion of transaminitis. That can only be true if the risk disclosures' failure to discuss the risk of transaminitis implied that the risk did not exist. Under *Rigel*, that is not a viable inference.

Even if it were, the complaint suffers from a second, factual defect. It does not plausibly plead that transaminitis was inevitable. In SEPTA's telling, that transaminitis was "virtually certain" to disrupt the STRIDES trial is evident from three sources: (1) the manifestation of transaminitis during a 2018 Amgen-led Phase 1 trial of azelaprag, (2) the manifestation of transaminitis in mice during one of BioAge's preclinical studies, and (3) the design of the STRIDES trial itself. None make the asserted inevitability of transaminitis in the STRIDES trial plausible.

First, SEPTA avers that in one Phase 1 trial, a single participant experienced a grade two (out of five) increase in a liver enzyme called aspartate aminotransferase and a grade one increase in another liver enzyme called alanine aminotransferase. CAC ¶ 75–76. That hardly establishes that transaminitis was "virtually certain" to derail the STRIDES trial. As SETPA acknowledges, the eight Phase 1 clinical trials involved 265 participants, yet only *one* manifested any increase in liver enzyme levels. Even in that single instance, the increase "did not require any treatment" and "was reported as resolved . . . 22 days after the last dose of the investigational product." CAC ¶ 75. It was so insignificant that it appears to have caused no disruption to Amgen and BioAge's Phase 1 trials.

Though SEPTA asserts that BioAge "had a duty to disclose to investors that liver transaminitis had occurred in a prior Phase 1 study of azelaprag," Opp., at 15, it fails to show that

the offering documents' discussion of the Phase 1 trial results was misleading without it. Discussing the results of the Phase 1 trial, the offering documents represented that the "overall adverse event profile of azelaprag was comparable to placebo, with no treatment-related trends in adverse events observed, with the exception of mild, self-limited headaches. No serious adverse events have been reported." CAC ¶ 54. That was not false or misleading. One observation of transaminitis does not make a "trend[]," and that observation was definitionally not "serious." *See* CAC ¶ 72 ("describing a grade 1 event as one that "causes mild effects" and a grade 2 event as "moderate" with "minimal, local or noninvasive intervention indicated"). Certainly, that isolated observation did not make it likely, much less inevitable, that the STRIDES trial would be impacted by transaminitis.[1]

SEPTA's second argument fares no better. It faults BioAge for failing to disclose that, in a 27-week mouse study, "BioAge purposely tracked liver enzyme levels in mice being dosed with azelaprag as a monotherapy and, in doing so, identified elevated liver enzyme levels in a cohort of high-fat diet mice receiving azelaprag." Opp., at 20. The import of that omission is unclear. The 27-week mouse study tested three cohorts of mice: (1) those on a high-fat diet receiving azelaprag, (2) those on a high-fat diet not receiving azelaprag, and (3) a lean-diet control group. CAC ¶ 61. While, as expected, those on a high-fat diet showed elevated liver enzyme levels compared to those on a lean diet, the mice on a high-fat diet that received azelaprag recorded *lower* liver enzyme levels than those on a high-fat diet that did not receive azelaprag. *See id.* SEPTA's assertion that "the cohort that was fed a high-fat diet and received azelaprag showed higher

[1] SEPTA also appears to argue that the offering documents' discussion of the Phase 1 trial results was false because the individual that experienced the grade 1 and grade 2 liver enzyme episodes simultaneously experienced a grade 4 increase in blood creatine phosphokinase, a muscle enzyme. *See* CAC ¶ 75. A grade 4 event indicates "life-threatening consequences" and necessitates "urgent intervention." *Id.* ¶ 76. Even if omitting that observation rendered the offering documents' description of the Phase 1 trial results false or misleading, SETPA suffered no damage from that misstatement. SEPTA does not allege that an increase in muscle enzymes levels had anything to do with the drop in BioAge's stock price as it was not the reason BioAge terminated the STRIDES trial, and Section 11 limits damages to those "resulting from" the false statement or actionable omission. 15 U.S.C. § 77k(e).

elevated liver enzyme level[s] than the mice on the lean diet without azelaprag," Opp., at 23, is a comparison of apples to oranges. Nothing in that mouse study suggested that azelaprag caused transaminitis. In fact, the opposite appears to be true.

Perhaps recognizing its misconstruction of the scientific method, SEPTA avers that the mere fact that BioAge tested liver enzyme levels in this mouse study "demonstrate[s] that elevated liver enzymes are a typical or expected result" of azelaprag. CAC ¶ 61. That, too, is misguided. BioAge's decision to monitor liver enzyme levels in this longitudinal mouse study shows, at most, that BioAge *once* considered meaningful the risk that azelaprag would cause transaminitis. When the results of the study revealed just the opposite, BioAge likely changed its hypothesis. Nothing about the mouse studies would have indicated that transaminitis was inevitable in the STRIDES trial.

Finally, SEPTA contends that the design of the STRIDES trial made transaminitis "virtually certain" to occur amongst the trial's participants. The design flaws SEPTA identifies include: (1) failure to exclude participants with unknown or undiagnosed fatty liver disease, a risk factor for transaminitis; (2) failure to instruct participants to not do physical exercise, take over-the-counter medicines such as acetaminophen or naproxen, or consume alcohol—all of which can increase the risk of transaminitis; (3) testing azelaprag alongside tirzepatide, which can cause elevated liver enzymes either alone or in combination with azelaprag; (4) attempting to stimulate weight loss, which itself can cause elevated liver enzymes. *See* CAC ¶ 85–91.

The averments in the complaint point to design features that made it *more likely* transaminitis would appear, but they do not plausibly demonstrate that transaminitis was inevitable. At various points, SEPTA's papers nearly concede as much. *See, e.g.*, Opp., at 12 ("[T]ransaminitis is a common health condition . . . that . . . *can* be triggered by numerous factors in the STRIDES trial.) (emphasis added); *Id.*, at 15 (describing the risk of transaminitis in the STRIDES trial as "*particularly acute* given the combination of obese trial participants and the agents . . . being utilized") (emphasis added); CAC ¶ 89 ("[N]owhere in the Offering Documents was it disclosed that significant or rapid weight loss *can* also elevate liver enzymes.") (emphasis

added).

As a last ditch, SEPTA avers that transaminitis had materialized in the STRIDES trial's participants by the time of the IPO. CAC ¶ 108–11. That averment is entirely conclusory. Though it claims to be based on "the proximity of BioAge's disclosure of elevated liver enzymes to the commencement of the IPO, the sheer number of trial participants, the commencement of trial dosing no later than July 29, 2024, the likely duration of time between initial dosing and the onset of elevated liver enzymes, the design protocol requiring periodic testing of liver enzymes, and the number of trial participants BioAge contended experienced the transaminitis side effect," SEPTA provides no detail about any of those factors that would permit an inference that transaminitis was observed in the STRIDES trial prior to the IPO. It is unclear, for example, how long the onset period is or how often BioAge was testing liver enzyme levels. Without that detail, SEPTA's claim is too speculative to survive a motion to dismiss.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is granted. SEPTA is granted leave to amend its complaint to cure the deficiencies recognized in this order. Any amended complaint must be filed within 21 days of the date of this order.

IT IS SO ORDERED.

Dated: October 30, 2025

RICHARD SEEBORG
Chief United States District Judge

United States District Court
Northern District of California